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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,687	02/10/2004	Gregory B. Altshuler	105090-0236	3813
21125	7590	01/22/2007	EXAMINER	
NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			JOHNSON III, HENRY M	
			ART UNIT	PAPER NUMBER
			3739	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/22/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)
	10/776,687	ALTSHULER ET AL.
	Examiner	Art Unit
	Henry M. Johnson, III	3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 November 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-3,9-11,15,17,21-25,27 and 31-80 is/are pending in the application.
 - 4a) Of the above claim(s) 52-80 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3,9-11,17,21-24 and 31-51 is/are rejected.
- 7) Claim(s) 15,25 and 27 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 14 July 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| <ol style="list-style-type: none"> 1)<input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3)<input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____. | <ol style="list-style-type: none"> 4)<input type="checkbox"/> Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____. 5)<input type="checkbox"/> Notice of Informal Patent Application 6)<input type="checkbox"/> Other: _____. |
|---|--|

DETAILED ACTION***Response to Arguments***

Applicant's arguments filed November 24, 2006 have been fully considered but they are not persuasive. Radiating facial tissue from within an oral cavity is related to intended use of the apparatus with no positive structure required. Any radiation device is inherently capable of radiating any tissue to which it is directed. Chen specifically teaches a device for photodynamic therapy with wavelengths from 280- 3000 nanometers, intensities from 1- 10,000 mW/cm² and fluences from 1-1000 J/cm². These are within the ranges cited by the applicant for the phototherapy. Further, a skilled artesian would select the wavelength and intensity based on the target chromophore as discussed by the applicant in paragraph 0073 of the specification.

Election/Restrictions

Newly submitted claims 52-80 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the inventions are distinct as an apparatus and method of use.

Since applicant has received two previous actions on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 52-80 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

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Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 17 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/776936.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they represent a minor, obvious change in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented (note that a notice of allowance is pending).

Claim 21 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/776686.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they represent a minor, obvious change in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented (note that a notice of allowance is pending).

Claim Objections

Claim 15 is objected to because of the following informalities: Markush claims require the wording "selected from the group consisting of".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the emitter" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 2 recites the limitation "the emitter" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 3 recites the limitation "the emitter" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation "the emitter" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 28 recites the limitation "the device" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 9, 28, 31-35, 38-44 and 48-51 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/06456 to Chen et al. Chen et al. teach an apparatus employing light

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therapy to treat oral conditions (abstract) including a mouthpiece that surrounds the teeth and gums (Fig. 2) that may be comfortably left inside a patient's mouth for extended times (page 2, lines 32-35) and is made from an elastomeric material such as silicone (page 5, line 8). This is interpreted as a compliant mouthpiece. The radiation source is disclosed as an LED, laser diode, gas discharge lamp or filament bulb (page 3, lines 30-32). The source may be mounted on the mouthpiece or located external to the mouthpiece with the radiation delivered via fiber optics (optical element). The means for delivery may include diffusing material (page 3, line 25). The optical fibers deliver the radiation in different directions (page 6, lines 13-15). Portions of the mouthpiece may be highly reflective (page 7, line 21). The sources mounted around the mouthpiece clearly radiate in different directions. The position of the mouthpiece during use is based on a methodology or intended use. Positioning the mouthpiece differently than disclosed by Chen et al. would inherently be capable of directing radiation in a direction of other tissue areas. Chen specifically teaches a device for photodynamic therapy with wavelengths from 280- 3000 nanometers, intensities from 1- 10,000 mW/cm² and fluences from 1-1000 J/cm². The apparatus is "U" shaped. Chen et al. incorporates by reference U.S. Patent 5,445,608 (also Chen et al.) that teaches the use of either an internal or external array of light sources and allows use of LEDs or laser diodes operating at two or more wavelengths, and the ability to selectively activate the sources operating at a given wavelength or waveband as desired, so that the light at the different wavelengths or wavebands is provided to the treatment site either sequentially or simultaneously from the light sources (Col. 8, lines 37-45). The sources may be controlled by monitoring the temperature rise of the tissue (diagnostic sensor) (Col. 8, line 8). The current regulation will control the power of the light source. In addition to multiple wavelengths, Chen et al. '608 further teaches other aspects of phototherapy. The delivery of a

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photosensitizer directly to the treatment area via a port in the apparatus and the apparatus adapted to use heat from the radiation source to heat the treatment area.

Regarding claim 9, the device is capable of radiating areas other than the teeth and gums and such radiation is related to the intended use of the apparatus.

Claims 1, 10-11, 23 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,862,771 to Muller. Muller teaches a toothbrush with a head with bristles and a radiation source in a handle. The location in the handle is disclosed as convenient if the toothbrush is an electrical toothbrush, i.e. having electrical drive means to move the cleaning

bristles in a tooth cleaning operation. The electric drive is interpreted as a vibrating mechanism. The radiation is directed in a direction parallel to the bristles either between the bristles or through the optically transparent bristles, thus teaching a plurality of emitters (Fig. 6). The bristles are

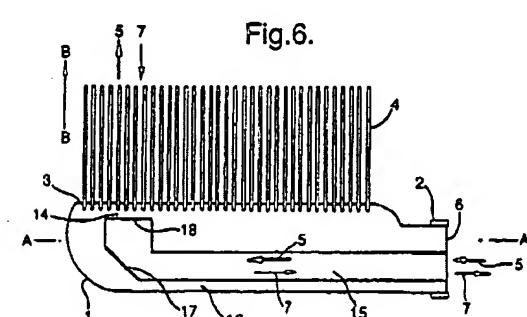


Fig. 6. The diagram illustrates a cross-section of a toothbrush head. At the top, a bundle of bristles is shown, with two points labeled 'B' on the left and one point labeled 'A' on the right. Below the bristles, a horizontal band labeled '18' contains several small circular elements labeled '5'. A central vertical line labeled '7' extends downwards. The base of the head is labeled '2' and '6'. At the very bottom, there is a rectangular component labeled '14' containing a small rectangular area labeled '18'. Below this, the numbers '17', '16', and '15' are visible. Arrows indicate the flow of radiation from the source at 'A' through the transparent bristles towards the bristles at 'B'.

interpreted as optical elements and capable of radiating in multiple directions as they are deflected during brushing, including a direction toward non-oral tissue. A reflecting surface directs the radiation to the bristles (Fig. 6, # 17). Along with the radiation source in the handle, a detector is disclosed for sensing reflected radiation. This detector is interpreted as a diagnostic sensor (Col. 2, lines 38-65). The radiation source may be a light emitting diode (LED) of known type and filters and mirrors are disclosed in the optical path. The detection means and an appropriate power supply, electronic processing devices (control), and means to signal the presence and/or absence of biological deposits on a tooth surface may conveniently be provided within the handle of the toothbrush (Col. 8, lines 35-50). A lens may be used in the optical path (Col. 12, line 38) and this is interpreted as a diffuser as lenses may diverge a beam,

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effectively diffusing the beam. The bristles have a core made of a transparent plastic material, surrounded by a sheath also of a transparent plastic material with a lower refractive index than that of the core. Alternatively the sheath may be thin coating of a shiny metal, e.g. 2-3 microns thick (col. 13, lines 12-17). The head is disclosed as being detachable (Col. 8, line 55).

Claims 1, 22 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,572,637 to Yamazaki et al. Yamazaki et al. teach a handheld light treatment device with a cylindrical adjuster (Fig. 2, # 20) to delivery the radiation to an area. The adjuster is interpreted as being capable of insertion into a mouth and capable of directing radiation in the direction of non-oral tissue. The adjuster may be equipped with an extra microswitch responsive to adjuster's touching the skin for making the electric power supply to turn on, and responsive to adjuster's leaving the skin for making the electric power supply to turn off (Col. 3, lines 23-30). The radiation source is cooled by a heat sink (Fig. 2, # 18) and a fan is provided in the handheld unit (Fig. 2, # 14).

Claims 1, 36 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,443,978 to Zharov. Zharov teaches a photomatrix device for irradiation of tissue using multiple LEDs that may be of different wavelengths (Col. 12, lines 1-5). A configuration is disclosed for use in a mouth (Col. 12, line 41). The device may include an ultrasonic module (Claim 61), the ultrasonic also interpreted as a vibrating element.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/06456 to Chen et al. Chen et al. are discussed above, but do not teach specific wavelength bands. A skilled artisan using photodynamic therapy would select the wavelength or wavelengths dependent on the specific procedure and target chromophore. Further, the applicant has not disclosed any unexpected results or criticality associated with the specific wavelengths. Therefore, the selection of the photodynamic wavelengths is considered a routine design choice by one of skill in the art.

Allowable Subject Matter

Claims 15, 25 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 15, 25 and 27 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 17 and 21 would be allowable by filing a terminal disclaimer as cited above.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Henry M. Johnson, III
Primary Examiner
Art Unit 3739